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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,604	08/30/2007	Masao Daimon	295889US0X PCT	2488

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EXAMINER	
MACFARLANE, STACEY NEE	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
03/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/591,604	DAIMON ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, drawn to an anti-brain-derived neurotrophic factor (BDNF) antibody.

Group II, claim(s) 4-6, drawn to a diagnostic kit comprising an anti-BDNF antibody and a labeling agent.

Group III, claim(s) 7-10, drawn to a method for assessing risk of an ischemic heart disease comprising measuring BDNF concentration in blood.

Group IV, claim(s) 11, drawn to a therapeutic drug comprising a compound that increases BDNF.

Group V, claim(s) 12 and 17, drawn to a therapeutic drug comprising BDNF.

Group VI, claim(s) 13, drawn to the use of a compound that increases BDNF in the production of a therapeutic drug for ischemic heart disease.

Group VII, claim(s) 14, drawn to the use of BDNF in the production of a therapeutic drug for ischemic heart disease.

Group VIII, claim(s) 15, drawn to a method for treating ischemic heart disease comprising administering a compound that increases BDNF.

Group IX, claim(s) 16, drawn to a method for treating ischemic heart disease comprising administering BDNF.

Group X, claim(s) 18, drawn to use of BDNF for the production of a drug that prevents post-infarction myocardial remodeling.

Group XI, claims 19, drawn to a method for suppressing/preventing post-infarction myocardial remodeling comprising administering BDNF.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the general inventive concept that permeates the groups is an anti-BDNF antibody (claim 1) and assay methods characterized by measuring BDNF concentrations in blood (claim 7). The expression "special technical feature" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions makes over the prior art. Whether a particular feature makes a contribution over the prior art, is considered with respect to novelty and inventive step. In the instant application, both the anti-BDNF antibody and the assay comprising measuring BDNF serum levels do not make a contribution over the prior art. The following reference teaches the purification and identification of BDNF from human serum using an anti-BDNF antibody (Rosenfeld et al., Protein Expression and Purification, 6(4): 465-471, August 1996). The prior art recites the common technical feature of Groups I-XI, thus, there is no special technical feature over the prior art and the application is found *a priori* to lack Unity of Invention under PCT Rule 13.1.

Furthermore, pursuant to 37 C.F.R. § 1.475 (a), Unity of invention before the International Searching Authority, an international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). When an application

contains claims drawn to different categories of inventions (i.e. methods and products) 37 C.F.R. § 1.475 (b) states that unity of invention exists if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

The inventions of Groups I-XI are drawn to *multiple* materially different products, such as, the anti-BDNF antibody (Group I) and the therapeutic drug comprising a compound that increases BDNF (Group IV); and *multiple* methodologically and materially distinct processes, such as, methods of screening versus methods of treatment. Thus, as claimed these inventions of the instant application do not fall into one of the combinations that the ISA/US considers as supporting Unity of Invention.

The inventions are independent or distinct, each from the other because:

The inventions of Groups I, II, IV and V are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use

together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are each structurally distinct. The antibody of Group I and the therapeutic drug comprising the protein BDNF (Group V) are specialized protein structures that are materially distinct and subserve distinct physiological functions. Structurally, antibodies are unique from other proteins in that they are comprised of 4 specialized protein chains linked by disulphide bonds. Antibodies mediate not only specific binding to their target markers but they expedite the immunologic complement signaling cascade, the likes of which are distinct in mode and effect, from that of other protein signaling. Additionally, the pharmaceutical compound of Group IV is distinct in structure and function from BDNF and anti-BDNF antibodies. Compounds may comprise of any number of bio-affecting natural or synthetic molecules. The inventions of Groups I, II, IV and V do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions of Groups III and VI-XI are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are directed to different methods that recite structurally

and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions. The instant specification does not disclose that these methods would be used together. The methods of Groups III and VI-XI are all unrelated as they comprise distinct method steps and utilize different products, which taken together, demonstrates that each method has a different mode of operation. Each invention performs its function or specific utility using structurally and functionally divergent material. Moreover, the methodology and materials necessary for, assessing risk of heart disease comprising measuring serum BDNF (Group III) differ significantly from methods of preventing post-infarction remodeling comprising administering BDNF (Group XI), for example. Searching the inventions of Groups III and VI-XI all together would impose serious search burden. Moreover, in the instant case, the searches for each claimed method are not coextensive in that prior art which teaches a method for using a compound that increases BDNF in the manufacture of a drug (Group VI) would not necessarily be applicable to the methods of treatment comprising administering BDNF itself (Group XI), for example. For these reasons the Inventions III and VI-XI are patentably distinct.

Invention of Groups IV and the Invention of Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In

the instant case the compound, as claimed, can be used in a materially distinct method such as in the manufacture of a drug (Group VI).

Invention of Groups V and the Inventions of Group IX and XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case BDNF, as claimed, can be used in materially distinct methods such as in the manufacture of a drug (Group VII), or the treatment of heart disease (Group IX), which is methodologically distinct from methods of preventing myocardial remodeling (Group XI).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply:

The inventions would employ different search strategies/queries in that the inventions are each materially and/or methodologically distinct. Additionally, the prior art applicable to one invention would not likely be applicable to another invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-R 5:45 to 3:30, TELEWORK-Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

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Examiner, Art Unit 1649